CSAT Guidelines for the Accreditation of Opioid Treatment Programs

Technical Amendments to Guidelines

The following four technical amendments conform the "CSAT Guidelines for the Accreditation of Opioid Treatment Programs" with the opioid treatment final rule published January 17, 2001 (66 FR 4076, January 17, 2001).

Item 1.

VI. Patient Medical and Psycho-social Assessment

A. Levels of Assessments/Evaluations (page 10) [section 8.12(e)(2)]

2. …"Programs complete a full medical evaluation within 14 days following admission."

Item 2.

VII. Guidelines for Therapeutic Dosage

B. Maintenance Therapy (page 12) [section 8.12 (h)(3)]

Delete the following (on page 13):

"7. The ordering physician shall ensure that the justification for daily doses above 100 mg are documented in the patient's record."

Item 3.

X. Unsupervised Approved Use ("Take-Home" Medication) (page 16) [section 8.12(h)(4)]

Replace item 2 (on page 17) with the following:

"2. Unsupervised or "take-home" use. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(a) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

If it is determined that a patient is responsible in handling opioid drugs, the following restrictions apply:

(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph 2(a), above) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision.

(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph 2(a), above) is two doses per week.

(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph 2(a), above) is three doses per week.

(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of

take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum 1-month supply of take-home medication, but must make monthly visits."

Item 4.

Section XIV. Special Considerations

H. Adolescents (page 23) [section 8.12 (e)(2)]

In item 1, replace the last sentence as follows:

"No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment."

CSAT GUIDELINES FOR THE ACCREDITATION OF OPIOID TREATMENT PROGRAMS

Introduction

In 1995, the Institute of Medicine (IOM) published its report on *Federal Regulation of Methadone Treatment*. Phil Lee, M.D., the Assistant Secretary for Health, asked the Federal Interagency Narcotic Treatment Policy Review Board (INTPRB) to study the IOM report and to determine the extent to which the IOM's recommendations should be accepted. The INTPRB is a Federal committee which functions to consider and resolve issues involving law enforcement, regulation, treatment, and policy issues regarding narcotic treatment. The INTPRB includes representatives from the National Institute on Drug Abuse (NIDA), the Food and Drug Administration (FDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Office of the Secretary of the Department of Health and Human Services, the Drug Enforcement Administration (DEA) in the Department of Justice, and the Office of National Drug Control Policy (ONDCP). After studying the report, the INTPRB recommended that the Federal oversight of opioid treatment should be changed to a regulatory model that would incorporate accreditation. Also in accordance with the IOM recommendation that a lead agency should be designated for Federal methadone treatment oversight, Dr. Lee designated SAMHSA as the lead agency in these efforts. The Center for Substance Abuse Treatment in SAMHSA was tasked with exploring implementation of this new regulatory/accreditation system.

On December 4–6, 1996, Joyce M. Johnson, D.O., M.A., Assistant Surgeon General and Director of the Office of Pharmacological and Alternative Therapies at the Center for Substance Abuse Treatment (CSAT), convened a special field-based Guideline Development Panel of pharmacotherapy experts to provide content input to CSAT as it began the process of developing guidelines for accreditation organizations. J. Thomas Payte, M.D., Medical Director of Drug Dependence Associates and Co-Chair of the American Society of Addiction Medicine's Committee on Methadone Treatment, chaired the Panel.

Approach to Guideline Development

The Development Panel used a modified consensus approach, based on CSAT's Treatment Improvement Protocol (TIP) process, to produce its guidelines for accreditation. As a first step, the Chair devised a preliminary outline for the Development Panel's work that was shared first with a Resource Panel of Federal and non-Federal experts on November 13, 1996. The Resource Panel's task was to

- ensure that the outline's content reflected issues to be covered by the guidelines and
- nominate potential members of the Guideline Development Panel.

Once the Resource Panel approved the outline, the Chair began contacting potential Development Panelists and, as they agreed to participate, assigned them to one of three workgroups. Each workgroup was responsible for developing the draft accreditation guidelines that pertained to specific portions of the content outline. A draft document was provided to CSAT in July 1997. An Expert Review Panel was held on January 14, 1998, to provide a secondary review and to refine the document further. In addition, this document was circulated for review and comment to additional treatment experts and Federal officials.

This report presents CSAT's guidelines for the development of an accreditation model for opioid (methadone and levo-alpha-acetyl methadol [LAAM]) treatment programs. This document will be provided to accreditation organizations that contract with CSAT for the purpose of accrediting opioid treatment programs. For some of the guidelines, CSAT believed a fuller explanation of the issue or rationale

underlying the standard was needed as well as some examples to clarify meaning. That information is presented in the box headed "Discussion."

Treatment Considerations Related to the Natural History of the Disease

The clinical assessment of all patients should take into account the natural history of opioid addiction as altered by time and treatment. Patients normally proceed from one stage of treatment to the next, or move back and forth among the naturally occurring stages. **Treatment tasks are determined in relation to the patient's stage in the disease.**

The stages of methadone/LAAM therapy are listed below. It is important at all stages that psycho-social, as well as medical treatment, be of sufficient intensity and duration to be effective.

1. Initial treatment: consisting of intensive assessment and intervention, from 3 to 7 days in duration.

2. Early stabilization: from the third to seventh day of treatment through 8 weeks.

3. Long-term treatment: from the end of early stabilization for an indefinite period of time in either a program setting or in an office-based setting.

4. Medically supervised withdrawal with continuing care, if and when appropriate.

5. Immediate emergency treatment: provision of methadone/LAAM therapy in situations where access to a comprehensive treatment program is not feasible (e.g., emergency room, detention center, Acquired Immune Deficiency Syndrome [AIDS] hospice, inpatient hospital unit) for conditions such as pregnancy, HIV-spectrum disease, or other illnesses and psychiatric problems.

The patient's response to treatment determines her or his progression through the stages of treatment. Some patients may sometimes remain in one stage for a considerable period of time while, in contrast, others may progress very quickly. It is not uncommon for a patient to relapse. There is both an individual and public health advantage to maintaining a patient on medication even when psycho-social treatment may not be yielding optimum results.

Pharmacotherapy may benefit the individual patient even when he or she does not appear to be benefiting from other clinic services. Additionally, pharmacotherapy may benefit the patient who no longer needs ancillary services.

OPIOID TREATMENT ACCREDITATION GUIDELINES

I. Administrative Organization and Responsibilities

Administrative responsibilities, both for organizations and individual practitioners, are adequate to ensure quality patient care and to meet the requirements of the laws and regulations of the Department of Health and Human Services, Drug Enforcement Administration, and the States.

Physician authority over the medical aspects of treatment is essential. Physicians retain the autonomy to make continuing treatment decisions in accord with clinical course and emergent research findings.

A. Goals

Each treatment program shall have a statement of its goals for patient care.

B. Human Resources Management

Each treatment program has a plan to ensure that staffing patterns are appropriate and adequate for the needs of the patients being served.

II. Management of Facility and Clinical Environment

Each treatment facility

1. has sufficient space and adequate equipment for the provision of all specified services including diagnosis, evaluation, and treatment of other medical, psychiatric, and behavioral disorders if they are to be carried out on site.

2. is clean and well maintained, similar to and in accord with other treatment resources for different medical and behavioral disorders.

3. maintains documentation that it meets all local and State safety and environmental codes.

4. ensures protection of confidentiality including the use of locked files and the availability of private individual offices for counseling.

5. provides a warm and welcoming atmosphere in a therapeutic environment that is "conducive to rehabilitation…and conveys a sense of dignity and trust between program and patients" (TIP 1, *State Methadone Treatment Guidelines*, page 33).

6. will provide services during hours that meet the needs of the overwhelming majority of patients, including hours before and/or after the traditional 8:00 a.m. to 5:00 p.m. working day, when possible.

III. Risk Management and Continuous Quality Improvement

A. Legal Issues

Discussion: Many States already require written consent for all types of medical care. This is essential in a climate of increasing patient litigation and questions from insurers. Requests from managed care groups for treatment records which are needed to recertify patients for payment require strict attention to Federal confidentiality regulations. Ethical conduct by staff and the program also requires attention and use of specific expectations and standards. Carefully specified grievance procedures are imperative and must be followed in all involuntary termination procedures. The currency of staff credentials may become a legal issue if someone is not properly licensed at the time of an incident or other adverse action.

Each treatment program

1. obtains voluntary, written, program-specific informed consent to treatment from each patient at admission.

2. informs each patient about all treatment procedures, services, and other policies and regulations throughout the course of treatment.

3. obtains voluntary, written, informed consent to the prescribed pharmacotherapy from each patient before dosing begins.

4. informs each patient of the following:

    a. that the natural history of opioid addiction is altered by time and history;

    b. that the goal of methadone/LAAM medication therapy is stabilization of functioning;

    c. that, at periodic intervals, in full consultation with the patient, the provider will discuss present level of functioning, course of treatment, and future goals. These discussions are in no way intended to place an unfair burden or pressure on the patient to withdraw from or maintain the patient on the medication unless medically indicated.

5. informs each patient at admission about State-specific requirements and program policies regarding the report of suspected child abuse and neglect as well as other forms of abuse (e.g., violence against women).

6. adheres to all requirements of the Federal confidentiality regulations (42 CFR Part 2).

7. promulgates and makes available a written description of patients' rights and responsibilities.

8. follows due process procedures for any involuntary terminations of patients.

9. develops credentialing procedures to ensure that all staff maintain current credentials for performing their assigned job responsibilities.

B. Life Safety Issues

Each treatment program

1. develops procedures to ensure that the correct dose of medication(s) is administered and that appropriate actions are taken if a mistake is made, including a mechanism for reporting untoward incidents to appropriate program staff.

2. maintains an up-to-date plan for emergency administration of medications in case the program must be closed temporarily, including how patients will be informed of these emergency arrangements.

3. provides 24-hour, 7-day per week access to designated program staff, so that patient emergencies may be addressed and dosage levels may be verified. Displays in facility offices and waiting areas the names and telephone numbers of individuals (e.g., physicians, hospitals, emergency medical technicians [EMTs]) who should be contacted in case of an emergency.

4. ensures that there are appropriately trained staff on duty who are trained and proficient in cardiopulmonary resuscitation (CPR), management of opiate overdose, and other techniques as appropriate.

5. develops and maintains an up-to-date disaster plan that specifies emergency evacuation procedures, fire drills, and maintenance of fire extinguishers.

6. establishes policies and procedures that address safety and security issues for patients and staff, including training for staff to handle physical or verbal threats, acts of violence, inappropriate behavior, or other escalating and potentially dangerous situations, with emphasis on when security guards or police need to be summoned.

C. Continuous Quality Improvement Policies

Each treatment program

1. provides regular and continuous staff education.

2. maintains staff development plans.

3. reviews and recertifies program policies and procedures at least annually.

4. elicits ongoing input into program policies and procedures by patients in consideration of community concerns.

5. develops and implements periodic patient satisfaction surveys.

6. adheres to universal infection control precautions promulgated by the CDC.

7. measures and monitors treatment outcomes and processes such as:

    - reducing or eliminating the use of illicit opioids, illicit drugs, and the problematic use of licit drugs;
    - reducing or eliminating associated criminal activities;
    - reducing behaviors contributing to the spread of infectious diseases;
    - improving quality of life by restoration of physical and mental health and functional status.

8. develops a diversion control plan that demonstrates accountability to its patients and to the community.

D. Adverse Events

> Discussion: The specific adverse events requiring preventive action, documentation, investigation, and corrective action will vary by program and patient characteristics. Such significant incidents or adverse events might include medication errors, patient deaths, harm to family members or others from ingesting a patient's medication, selling drugs on the premises, medication diversion, harassment or abuse of patients by staff, and violence. An accreditation organization should consider making an unannounced visit to a treatment program if it determines that an adverse event involves immediate threat to the care or safety of an individual, the adverse event is believed to indicate the possibility of serious operational or personnel problems in the treatment program, there has been more than one serious adverse event in 6 months, or the adverse event has the potential to undermine public confidence in the treatment program.

Each treatment program

1. establishes procedures to guard against adverse events that could have a negative impact on patients and their family members, the program, or staff. This includes events that involve the loss of life or function of an individual served.

2. establishes procedures, in case a specified or unanticipated adverse event occurs, to ensure

    a. full documentation of the adverse event;

    b. prompt investigation and review of the situation surrounding the event;

    c. implementation of timely and appropriate corrective action(s);

    d. ongoing monitoring of any corrective actions until their effectiveness is established.

IV. Professional Staff Credentials and Development

Each treatment program shall ensure

1. doctors, nurses, and other licensed professional care providers maintain their current license and comply with the credentialing requirements of their own professions. Specific credentialing by any formal body for work in addictions is desirable but not essential.

2. addictions counselors meet the qualifications outlined by the employing program and the State.

3. all staff receive initial education specific to the pharmacotherapies to be used and tailored to the patient populations to be served.

4. all staff receive continuing education. Staff may be qualified by training, education, and/or experience.
5. an individual annual training plan is implemented.

6. detailed job descriptions are developed for credentialed and noncredentialed staff which clearly define the qualifications and competencies needed to provide specific services.

7. records are kept of staff training events, including the qualifications of educators, outline of content, description of methods, and attendees; records of staff training events should be kept in personnel files.

8. access to resources for problem solving and troubleshooting.

V. Patient Admission Criteria

A. Evidence of Current Physiological Dependence and Opioid Addiction

1. Program physician must document that treatment is medically necessary.

2. Criteria for admission should be based on DSM IV definition of opioid dependence.

3. Behavior supportive of a diagnosis of addiction includes:

    a. continuing use of the opiate despite known adverse consequences to self, family, or society;

    b. obtaining illicit opiates;

    c. using prescribed opiates inappropriately;

    d. one or more unsuccessful attempts at gradual removal of physical dependence on opioids (detoxification) using methadone. When supervised by a physician, this is called medically supervised withdrawal (MSW). An unsuccessful attempt at MSW is evidenced by uncontrollable drug craving (or actual use) caused by insufficient methadone dose during an admission for detoxification or MSW. There should be no artificial barrier created nor should there be a set amount of time that separates the transfer from an unsuccessful attempt at detoxification or MSW directly into the early phase of methadone/LAAM maintenance treatment.

4. There may be individuals in special populations who have a history of opioid use but who are not currently physiologically dependent. The absence of physiological dependence should not be an exclusion criterion, and admission is clinically justified. This is because individuals in these populations are susceptible to relapse to opioid addiction leading to high-risk behaviors with potentially life-threatening consequences. These populations include the following:

    a. persons recently released from a penal institution;

    b. persons recently discharged from a chronic care facility;

    c. pregnant patients;

    d. previously treated patients;

    e. adolescents.

B. Avoiding Multiple Program Enrollments

Reasonable measures are taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner. These measures are commensurate with the severity of the problem and its documented consequences.

Programs should be encouraged to participate in central registries designed and implemented by the State.

VI. Patient Medical and Psycho-social Assessment

The purpose of an assessment is to determine treatment eligibility, develop a treatment plan, and establish a measure for the response to treatment. For all applicants initially deemed eligible for opioid (methadone/LAAM) therapy, a comprehensive physical examination, laboratory workup as indicated, psycho-social assessment, preliminary treatment plan, and patient orientation are completed during the initial treatment stage.

A. Levels of Assessments/Evaluations

Discussion: The initial assessments focus on the patient's admission to treatment and determine dosage level. A more comprehensive examination is performed within approximately 30 days when the patient is stable and better able to participate. Other evaluations that may prove necessary include formal psychiatric and vocational assessments and ancillary medical workups. The program is responsible for arranging such evaluations and for follow-up. A patient re-entering treatment may need a repeat examination depending on the timing of the original exam. All patients also undergo periodic health assessments including regular screenings based on clinical guidelines as appropriate for age and gender.

Assessments generally comprise an intake screening assessment and an intensive initial evaluation. The screening is conducted to determine whether the patient may appropriately receive methadone/LAAM therapy. The intensive evaluation includes medical and health history and physical examination to determine initial dosage and place the patient into the appropriate level of treatment. Upon completion of proper patient consent, the program seeks medical records from other health care providers. The health history is used to determine the length of dependence for placement purposes and to identify other chronic or acute medical conditions that affect the patient's health.

Each program

1. determines current physical dependence and addiction. History, examination, and screening are used to determine the patient's current degree of dependence on narcotics and, to the extent possible, the length of time the patient has been dependent on opioids. This assessment includes a physical examination for the presence of clinical signs of addiction, such as old and fresh needle marks, constricted or dilated pupils, and/or an eroded or perforated nasal septum and a state of sedation or withdrawal. The examination evaluates the observable and reported presence of withdrawal signs and symptoms, such as yawning, rhinorrhea, lacrimation, chills, restlessness, irritability, perspiration, piloerection, nausea, and diarrhea.

2. documents medical and family history. A complete medical history is documented, including current information to determine chronic or acute medical conditions, such as diabetes, renal diseases, hepatitis B, C, and delta, HIV exposure, tuberculosis (TB), sexually transmitted diseases (STDs), other infectious diseases, sickle-cell trait or anemia, pregnancy (including past history of pregnancy and current involvement in prenatal care), and chronic cardiopulmonary diseases. Programs complete a full medical evaluation within 7 days of treatment initiation.

3. completes a psychiatric history and mental status examination with DSM-IV categorization (*Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition) as part of a general medical evaluation.

4. completes information on the patient's family, including sex and date of birth of children, whether children are living with parents, and family medical and drug use histories.

5. employs a multidisciplinary evaluation approach. Such an approach may be conducted by multidisciplinary team members. As an alternative, this evaluation may be conducted by one or more individuals, but must evaluate the following areas: medical, psycho-social, vocational, educational,

behavioral, marital, financial, legal, health, and self-care needs of patient. This evaluation should be conducted within approximately 30 days of initiation of patient treatment. Assessment updates and treatment plan updates should be conducted quarterly for the first year of continuous treatment and semiannually for subsequent years.

B. Medical Laboratory Evaluation/Diagnostic Criteria

1. Required tests

    a. TB skin test and chest x-ray if skin test is positive (including consideration for anergy),

    b. screening test for syphilis.

2. Recommended tests and assessments. Based on an individual's history and physical examination, programs investigate the possibility of infectious disease, pulmonary, cardiac abnormalities, dermatologic sequelae of addiction, and possible concurrent surgical and other problems by conducting

    a. CBC;

    b. EKG, chest x-ray, Pap smear, or screening for sickle cell disease;

    c. hepatitis B surface antigen (HbsAG) and hepatitis B surface antibody (anti-HBs);

    d. HIV testing (and counseling).

2. Urine drug-screening tests must be analyzed for opiates, methadone, amphetamines, cocaine, and barbiturates. Urine testing for other drug use should be determined by community drug use patterns or individual medical indications.

3. Other considerations include the following:

    a. Financial problems, transportation to referral sites, stress, and poor mental and physical well-being may be barriers to comprehensive laboratory testing upon admission. Other tests may be deferred until the patient has stabilized.

    b. Patients are usually in poor physical health and require other health care. Programs without primary care on site refer patients for laboratory tests and follow-up on results. Three months after admission is the optimal deadline for completing needed health-related procedures.

VII. Guidelines for Therapeutic Dosage

Discussion: The thrust of these guidelines was to keep the dosage guidelines for maintenance therapy as simple as possible, with broad latitude for exercising clinical judgment and minimal mention of dosage amounts or schedules. CSAT decided not to elaborate on the advisable waiting time before administering additional incremental doses of methadone after the initial dose, or to specify the amounts of any additional doses, although they did offer fairly specific guidelines for initial dosing. Subsequent dosing during the induction and stabilization periods is discussed in detail in the referenced *State Methadone Treatment Guidelines* (TIP 1).

A. General Dosage Principles

1. The dose of methadone/LAAM maintenance medication is individually determined on the basis of good clinical judgment after review by a physician or other professional practitioner with prescribing privileges who is knowledgeable about, and experienced in, addiction medicine including methadone/LAAM

therapy.

2. Methadone or LAAM maintenance medication doses are sufficient to produce the desired response in the patient for the desired duration of time, with allowance for a margin of effectiveness and safety.

3. Methadone/LAAM therapy has three desired clinical effects, which are, in ascending importance:

    a. preventing the onset of subjective and/or objective signs of opioid abstinence syndrome for 24 hours or more;

    b. reducing or eliminating the drug hunger or craving routinely experienced by the opioid-addicted individual when not in treatment;

    c. blocking the effects of any illicitly acquired, self-administered opioids without inducing persistent euphoric or other undesirable effects that are experienced by the patient or noticed by other observers.

B. Maintenance Therapy

1. A documented history and physical examination support the judgment by the physician that the patient is a suitable candidate for methadone/LAAM therapy.

2. The initial full-day dose of methadone is based on the physician's evaluation of the history and present condition of the patient, with added knowledge of such local conditions as the relative purity of available street drugs.

3. The usual initial dose of methadone should be from 20 to 30 milligrams. Reasons for exceeding an initial dose of 30 mg need to be carefully documented in the clinical chart and should not exceed 40 mg, unless the physician documents in the patient's record that 40 mg did not suppress opiate abstinence symptoms after a 3-hour period of observation. Addicted patients abusing diverted medical opioids alone may require a lower initial dose of methadone, and should have the initial dose of methadone based on standard dose conversion tables and their recent amount of opioid intake.

4. Initial dosing of LAAM and other approved medications should be based on the package insert. Deviations from this must be documented by the physician.

5. Induction and maintenance dosages follow the principles defined in TIP 1, *State Methadone Treatment Guidelines*, with particular attention to steady-state pharmacokinetics with accumulation during the induction process.

6. The maintenance dose is individually determined with careful and caring attention to the essential information provided by the patient; the dose should be determined by a physician experienced in addiction treatment and should be adequate to achieve the desired effects for 24 hours or more, with allowance for day-to-day fluctuations and elimination patterns.

7. The ordering physician shall ensure that the justification for daily doses above 100 mg are documented in the patient's record.

8. The total dose of methadone and the interval between doses may require adjustments for patients who have atypical metabolism patterns or are prescribed other concurrent medications which alter rates of methadone metabolism.

9. Methadone is a medication: It should not be standard practice to manipulate doses to reinforce positive behavior or to punish negative behavior. However, there are exceptions to this rule. For example, sometimes the patient's need for acute or emergency medical care may be urgent and may take precedence over the need for a single day's dose at the program.

10. Methadone is continued as long as benefit is derived from treatment and the treatment is desired by the patient.

11. Doses of methadone and LAAM or other approved medications are adjusted as needed if a program switches from one generic formulation to another and differences in effective dose cause clinically relevant complaints.

12. The program should have the capability of obtaining medication blood levels when clinically indicated.

C. Medical Withdrawal of Methadone or LAAM

Discussion: Methadone should not be considered to be a "toxic" substance; and from a medical perspective, *detoxification* is not an accurate term to use. The term "medical withdrawal" was chosen because it more accurately reflects the physician's role in withdrawal. These guidelines focus on patients who have been maintained on methadone or LAAM pharmacotherapy, rather than focus on issues of medical withdrawal of opioid-addicted persons who are not eligible for methadone/LAAM therapy, or who do not elect this type of treatment. Involuntary withdrawal or "administrative withdrawal" is addressed in the section on legal issues which requires that due process be defined and followed. No schedule for dose reductions will fit all patients; some individuals tolerate more rapid withdrawal than others. The underlying goal is to have voluntary medical withdrawal reflect a humane partnership between the patient and the physician.

Medical withdrawal refers to a medically supervised, gradual reduction or tapering of dose over time to achieve the elimination of tolerance and physical dependence to methadone or LAAM.

1. Voluntary withdrawal from methadone/LAAM therapy—as distinct from involuntary withdrawal and administrative withdrawal and other types of withdrawal discussed in Section XI—is initiated only when desired by the rehabilitated patient, in partnership with the physician.

2. If medical withdrawal is initiated, dosages of methadone or LAAM are reduced at a rate that is well tolerated by the patient and also in accordance with sound medical practices.
3. For women of childbearing potential, the results of a pregnancy test are reviewed before initiating medical withdrawal of methadone or LAAM.

4. Methadone/LAAM therapy is resumed in the event of impending relapse.

D. Pain Management in Maintenance Patients

1. Management of chronic pain in the methadone-maintained patient includes consultation with a specialist in pain medicine when possible and appropriate.

2. Management of acute pain in the methadone-maintained patient entails

    a. continuation of the regularly scheduled methadone dose.

    b. additionally prescribing adequate doses of appropriate medications, including short-acting methadone/LAAM medications; this is addressed in more detail in Section XIV, Special Considerations, Part E.

VIII. Treatment Planning, Evaluation of Patient Progress in Treatment, and Continuous Clinical Assessment

A. Intensity and Duration of Treatment

1. In general, a greater intensity of services is desirable at the beginning of treatment.

2. Psycho-social services are often needed by many patients for an extended period of time due to the multiplicity of their problems.

3. For long-term opiate addiction treatment, many patients need continuing medication with or without psycho-social services as outlined in TIP 20, *Matching Treatment to Patient Needs in Opioid Substitution Therapy*.

4. There are no limits on the duration or the dosage level of medication unless clinically indicated. Likewise, there are no limitations on psycho-social services offered even when patients are receiving "0" dose levels.

B. Retention in Treatment

Discussion: Studies suggest that the duration of retention in treatment is directly related to success in outcome (Gerstein et al., 1994; French et al., 1993; French and Zarkin, 1992; Institute of Medicine, 1990; Hubbard et al., 1989; Simpson et al., 1986). For patients who drop out of treatment, the outcome is usually negative, whereas patients who remain in treatment, despite continued excessive use of alcohol or illicit drugs, tend to benefit from the treatment experience.

1. Programs and individual practitioners make every effort to retain patients in treatment as long as clinically appropriate, medically necessary, and acceptable to the patient.

2. Appropriate therapeutic measures are taken to address the other problems identified in the treatment plan.

C. Relapse Prevention

1. Psycho-social treatment continues for patients electing to discontinue pharmacotherapy.

2. If possible, clinics and individual practitioners track patients and reinstitute pharmacotherapy at the first sign of relapse or impending relapse (see XI.C, "Support of Medical Withdrawal").

3. Some patients progress into long-term pharmacotherapy and no longer need psycho-social services. If the need for psycho-social services reemerges, however, programs provide the opportunity to return to full services.

D. Involvement of Family and Significant Others in Treatment

Treatment programs provide opportunities for family involvement in therapy.

IX. Testing for Drug Use

A. Urine drug screening (as well as other adequately tested toxicological testing procedures) is used as an aid in monitoring and evaluating a patient's progress in treatment within a context that assesses a variety of outcome measures.

B. All treatment personnel in a methadone/LAAM therapy program understand the benefits and the limitations of urine screening and other toxicological testing procedures.

C. Programs collect all urine or other toxicological specimens in a therapeutic context that suggests trust and respect and minimizes falsification. Reliance on direct observation, video camera monitoring, or one-way mirrors, although necessary for some patients, is neither necessary nor appropriate for all patients. Temperature testing is minimally intrusive and highly effective in identifying "counterfeit" or altered urine specimens.

D. Programs test urine samples for opiates, methadone, amphetamines, cocaine, and barbiturates at the minimum. Any additional testing is based on individual patient need and local drug-using conditions and trends, as well as access to funding. Treatment programs should make their laboratories aware of the fact that workplace testing standards for urine testing are not appropriate in the treatment context.

E. Program staff addresses results of urine screens promptly with patients to facilitate rapid intervention with any drug taking that was disclosed or possible diversion of methadone as evidenced by lack of methadone or its metabolites in the urine.

F. Programs conduct an initial urine or other toxicology test as part of the admission process. Thereafter, the frequency of urine screens or other toxicological testing is determined by the clinical appropriateness for each individual patient and related to the stage of treatment. Patients in the initial phases of treatment may require more frequent testing. During later phases of treatment, the testing schedule is reduced, but structured to ensure a rapid response to the possibility of relapse.

G. The results of urine or other toxicological tests assist clinical staff in making informed decisions regarding take-home medication privileges; however, clinical decisions about take-homes or discharge are not based solely on urine or other toxicology test reports.

H. Programs document both the results of urine tests and follow-up therapeutic actions in the patient record.

I. Treatment programs establish procedures for addressing potentially false positive and false negative urine or other toxicology test results following principles outlined in TIP 1, *State Methadone Treatment Guidelines*.

X. Unsupervised Approved Use ("Take-Home" Medication)

Providing medication for unsupervised use is a reflection of the physician's judgment and staff's assessment of a patient's behavior while in treatment. Time in treatment is also an important factor. "Take-home" medication is also a valuable therapeutic tool that often becomes a critical issue with patients deciding whether to enter and remain in treatment. Program staff use discretion in customizing medication schedules for each patient according to that patient's best interests. Public health issues should be considered in approving "take-home" medication (e.g., preventing diversion, ensuring safe storage and security of medication, preventing overdoses). Staff should ensure that policies for approval of "take-home" medication do not create barriers for patients continuing in treatment. Program policies foster decisions about entering and remaining in methadone/LAAM therapy that are based on medical factors.

A multidisciplinary team, typically led by the primary clinician, provides recommendations and essential

input for review, while a physician makes the final decision about approving "take-home" medication. Decisions should be reviewed periodically, at least every 90 days and more frequently if indicated, and documented in the patient record. The review should consider and evaluate drug testing results and other relevant clinical factors. The physician's conclusions on this review should be noted in the record.

A. Criteria for Approving "Take-Home" Medication

1. Programs consider the following criteria in determining patient eligibility for "take-home" medication:

    a. cessation of illicit drug use;

    b. regularity of program attendance;

    c. length of time and level of treatment in methadone/LAAM therapy (patient's ability to responsibly self-medicate);

    d. absence of known recent criminal activity (especially drug dealing);

    e. absence of serious behavioral problems;

    f. absence of abuse of drugs including excessive use of alcohol;

    g. other special needs of the patient, such as split dosing, physical health needs, pain treatment, etc.;

    h. capacity to safely store "take-home" medication within the patient's home;

    i. stability of the patient's home environment and social relationships;

    j. patient's work, school, or other daily life activity schedule;

    k. hardship experienced by the patient in traveling to and from the program.

2. Criteria for determining the number and quantity of "take-home" (unsupervised) doses per week include the following:

    a. first 90 days of treatment—maximum of one unsupervised dose per week;

    b. second 90 days of treatment—maximum of two unsupervised doses per week;

    c. third 90 days of treatment—maximum of three unsupervised doses per week;

    d. remainder of year one and year two—maximum of six unsupervised doses per week;

    e. year three—a maximum of 30 unsupervised doses per month.

3. One-time or temporary (usually not to exceed three days) "take home" medication may be approved for documented family or medical emergencies or other exceptional circumstances.

B. Monitoring Patients' Unsupervised Use of Medications

Discussion: To monitor patients receiving medication for unsupervised use, physicians need a thorough understanding of physiological issues, differences among laboratories, and factors that impact absorption, metabolism, and elimination of opiates. This knowledge is necessary to interpret a negative methadone urine test, for example.

1. Treatment programs monitor patient's prescribed "take-home" medications in a manner that complies with Federal regulations.

2. Program policies enable a physician to evaluate a patient's stability and response to "take-home" medication and to adjust dosages at regular intervals.

C. Medication Security

1. Program policies ensure responsible handling and secure storage of "take-home" medication in child-proof containers.

2. Programs inform patients of their rights and responsibilities in ensuring the security of opioid medications.

3. Programs shall establish a mechanism for monitoring medications to prevent diversion.

XI. Withdrawal and Discharge

A major goal for programs is to retain patients for as long as they can benefit from treatment and express a desire to continue it. Since this is not always possible, programs provide two types of withdrawal procedures: medical/therapeutic and administrative withdrawal. Medical/therapeutic is a voluntary, patient-initiated withdrawal. In contrast, administrative withdrawal is usually involuntary. However, in those cases where a patient must be administratively discharged from pharmacotherapy, the program offers a humane withdrawal schedule. The person's condition during medical or administrative withdrawal is periodically recorded in the patient's record.

A. Administrative Withdrawal

Discussion: In these examples, administrative withdrawal is ordinarily relatively brief, usually less than 30 days. Given the short time frame and the poor prognosis for the withdrawal procedure, patient referral or transfer to a suitable alternative treatment program is the preferred approach.

Administrative withdrawal may result from

1. nonpayment of fees. Remedies may include referral to a more affordable treatment program. As a last resort, programs provide a humane schedule of withdrawal.

2. disruptive conduct or behavior considered to have an adverse effect on the program, staff, or patient population of such gravity as to justify the involuntary withdrawal and discharge of a patient despite an extremely poor prognosis. Such behaviors include violence, threat of violence, dealing drugs, repeated loitering, flagrant noncompliance resulting in an observable, negative impact on the program, staff, and other patients.

3. incarceration or other confinement.

Efforts should be documented regarding referral or transfer of the person served to a suitable, alternative treatment program.

B. Medical Withdrawal

> Discussion: Medical withdrawal does not usually have the same time constraints that are associated with administrative withdrawal. As a result, programs can schedule a longer and more flexible dose reduction In the case of patient-initiated withdrawal, however, the patient may impose a time frame that may or may not impact the prognosis.

Medical withdrawal occurs

1. as a voluntary and therapeutic withdrawal agreed upon by staff and patient, or

2. in response to the request of the patient against the advice of the physician, counselor, and other staff; that is, against medical advice (AMA).

C. Support of Medical Withdrawal

The following program policies and procedures promote successful medical withdrawal whether conducted with or against medical advice:

1. Dose reduction occurs at a rate well tolerated by the patient.

2. A variety of supportive options are available to improve chances of a successful withdrawal.
3. Increased counseling is available prior to discharge.

4. Participants are encouraged to attend a self-help program that is sensitive to the needs of methadone/LAAM therapy patients.

D. Additional Considerations for Medical Withdrawal Against Medical Advice (AMA)

1. The patient has the right to leave treatment when he or she chooses to do so. The program explains the risks of leaving treatment.

2. The physician, in consultation with the patient, determines the schedule for withdrawal from methadone/LAAM therapy.

3. In the case of a patient who leaves a program abruptly, the program may readmit the patient within 30 days without a formal reassessment procedure.

4. The program documents the issue that caused the patient to seek discharge, and provides a full documentation of steps taken to avoid discharge.

E. Continuing Care

1. Continuing care is considered an essential part of treatment and includes discharge planning and relapse prevention.

2. Continuing care also includes procedures that address patients' physical and mental health problems following withdrawal from methadone/LAAM therapy, including the need for counseling and appropriate medication to help with sleep disorders, depression, and other problems.

3. Provisions are made for continuing care following the last dose of medication and for re-entry to maintenance treatment if relapse occurs.

XII. Management of Concurrent Alcohol and Polysubstance Abuse

A. Concurrent abuse of other drugs is managed within the context of the methadone/LAAM therapy effort following principles described in TIP 10, *Assessment and Treatment of Cocaine-Abusing Methadone-Maintained Patients*, and TAP 7, *Treatment of Opiate Addiction with Methadone*.

B. Program staff are knowledgeable about current, effective strategies for treating alcohol, cocaine, and other drug abuse.

C. Ongoing multi-drug use is not necessarily a reason for discharge unless the patient refuses recommended, more intensive levels of care. Patients engaging in such multi-drug use must be carefully evaluated to determine the most therapeutic course of treatment, in light of the fact that many patients (and communities) continue to benefit from methadone/LAAM therapy even when the patients are not fully abstinent from all drugs of abuse. In addition, the patient's condition and the best clinical judgment of the treatment team must also be taken into account.

D. When possible, comorbidities are concurrently managed on site. This includes management of multiple drug use problems as well as psychiatric and medical disorders. Coexisting conditions, especially in patients from disenfranchised populations, are most effectively treated at a single site.

XIII. Concurrent Services

A. Orientation to Treatment

Patients receive orientation to treatment initially and receive education on an ongoing basis about

1. signs and symptoms of overdose and when to seek emergency assistance;

2. the medication they are taking, including side effects and common myths about the medication or modality of treatment;

3. the nature of addictive disorders;

4. the benefits of treatment and nature of the recovery process;

5. clinic guidelines, rules, and regulations, including the requirement to sign a formal agreement of informed consent;

6. noncompliance and discharge procedures, including administrative medication withdrawal;

7. patient's rights;

8. confidentiality;

9. drug-screening and urinalysis procedures;

10. dispensing of medication;

11. HIV-spectrum and other infectious diseases;

12. potential drug interactions.

B. Substance Abuse Counseling

Appropriately trained, experienced, and qualified substance abuse counselors provide services of the intensity and duration required to meet the individual needs of the patient population. Staffing patterns are determined by the characteristics and needs of a particular patient population. Likewise, patient-staff ratios are sufficient to ensure reasonable and prompt access to counselors by patients and to provide the frequency and intensity of counseling services required.

C. Self-Help Groups

The use of self-help groups is encouraged but not required in pharmacotherapy. Traditional self-help groups are sometimes unfamiliar with maintenance patients. Programs can establish their own self-help programs or identify those groups that are accepting of maintenance pharmacotherapy.

D. Counseling on HIV Disease

1. Programs provide counseling on HIV disease and other prevalent infectious diseases and their prevention for every patient.

2. Programs provide risk reduction education to patients.

E. Medical Services

1. Providing basic primary care on site in clinics or in the individual practitioner's office is highly recommended but not required. Referrals for medical and psychiatric treatment shall be made when indicated. Coordination of care should also be provided, and those staff responsible for making linkages should be knowledgeable about pharmacotherapy treatment (e.g., drug interactions, acute withdrawal, and overdose). Medications which have their effectiveness enhanced by directly observed therapy (DOT)—such as tuberculosis medications and psychiatric medications—can be effectively dispensed with the daily opioid dose. Likewise, psychotropic medications, which are indicated but subject to abuse, may be given through DOT.

2. Programs train staff to respond to medical emergencies within the clinic or office environment and ensure that needed supplies are available.

XIV. Special Considerations

A. Care of Racial, Ethnic, and Sexual Minority Patients in Treatment

1. Programs develop and implement written, nondiscrimination policies to ensure equal access to treatment for all persons in need regardless of race, ethnicity, gender, age (with specific reference to policies for minors), and sexual orientation.

2. Programs are sensitive to the culture and values of the persons being treated.

3. Programs ensure that persons in positions of authority are professionally and culturally competent (for example, that these persons are able to work effectively with the local community and/or receive input

from advisors or committee members in the local community in terms of gender, ethnicity, and language or are representative of it).

4. Unbiased language is used in print materials, electronic media, and course offerings.

5. As appropriate, treatment is offered in groups organized by special needs (e.g., gender, sexual minority, seniors, Spanish language).

B. Care of Patients with Mental Health Needs

1. Programs ensure that patients with mental health needs are identified through the evaluation process and referred to appropriate treatment.

2. Program discharge procedures ensure that patients are monitored during withdrawal for emergence of symptoms of mental illness.

3. Programs establish and use linkages with mental health providers in the community.

4. Programs establish a mechanism to evaluate mental health medication jointly with the mental health provider. If possible and if indicated, programs may even dispense such medications in conjunction with the daily methadone dose.

C. HIV Testing and Care of HIV-Positive Patients

1. Programs develop and implement a plan for educating patients about HIV/AIDS, testing procedures, confidentiality, reporting, and follow-up care, counseling, safer sex, social responsibilities, and sharing of intravenous equipment.

2. Programs offer HIV-positive patients options to balance methadone/LAAM therapy and HIV/AIDS care and treatment.

3. Programs establish and use linkages with HIV/AIDS treatment programs in the community. These linkages should facilitate systems which continue opioid medication for debilitated patients and transfer care to primary physicians when AIDS becomes the primary health concern.

D. Alternative Therapies

Programs support patient choice in seeking alternative therapies while providing appropriate guidance in the process. Programs may provide culturally appropriate or popular and non-harmful alternative therapies as indicated (e.g., providing a space for sweat lodge ceremonies in a rural clinic serving Native Americans or offering acupuncture).

E. Pain Patients

1. Programs shall make careful diagnostic distinctions between the physical dependence associated with chronic administration of opioids for relief of pain and the disease of opioid addiction. Apparent drug-seeking behaviors, typically associated with the disease of chronic opioid addiction, may occur as a response to inadequately treated or prolonged pain ("pseudo-addiction"). The physical dependence and tolerance to opioids seen in some chronic pain patients are an expected physiological response to methadone/LAAM therapy and do not support a diagnosis of active opioid addiction.

2. Four of the seven criteria for "Substance Dependence" included in the *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)* are useful in differentiating chronic pain patients with opioid dependency problems who are most appropriate candidates for methadone/LAAM therapy. The relevant criteria are

    a. unsuccessful efforts to control use (loss of control);

    b. large amounts of time spent in activities to obtain or recover from effects; that is, compulsion (except as necessary to obtain pain relief);

    c. giving up or reducing important social, occupational, or recreational activities;

    d. continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (*DSM-IV*, p. 181).

3. Patients are generally not admitted to methadone/LAAM therapy to receive opioids only for pain.

4. Patients with a chronic pain disorder **and** physical dependence are managed by multidisciplinary teams that include pain and addiction medicine specialists. The site of such treatment may be either in a medical clinic or in a methadone/LAAM therapy clinic, depending on patient need and the best utilization of available resources.

5. Patients who are diagnosed with physical dependence and a pain disorder are not prohibited from

receiving methadone/LAAM therapy for either maintenance or withdrawal in a program setting if such setting provides expertise or is the only source of treatment. Similarly, addiction patients maintained on methadone/LAAM are not prohibited from receiving needed pain treatment including, when appropriate, adequate doses of opioid analgesics.

F. Emergencies

1. Programs develop and update regularly a disaster plan that includes links to community agencies and ensures emergency dosing.

2. Programs maintain a 24-hour telephone answering capability to respond to facility and patient emergencies. A roster of patients and a log of medication dosages are accessible to the staff person on call for verification purposes.

G. Voluntary and Involuntary Closure

1. Programs develop a plan to establish through State authorities or other governmental entities procedures to ensure continuity of care for patients in the event of voluntary or involuntary closure of programs or individual practices. The plan includes steps for the orderly transfer of patients, records, and assets to other programs or practitioners.

2. Programs develop a plan to ensure that patient records from programs that are closing are secured and maintained in accordance with State and Federal regulations for a specified period of time.

H. Adolescents

1. A person under 18 is required to have had two documented attempts at short-term medically supervised withdrawal (detoxification) or drug-free treatment to be eligible for maintenance treatment. The program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. No person under 18 years of age, except an "emancipated minor," may be admitted to a maintenance treatment program unless a parent, legal guardian, or responsible adult completes and signs the consent form, Form FDA 2635, "Consent to Methadone Treatment."

2. Programs tailor assessments to the developmental stage of the patient.

3. Programs develop and implement policies to ensure that adolescents are not harassed or exploited by older patients or staff.

I. Criminal Justice

1. Programs establish agreements and develop procedures to coordinate with agents of the criminal justice system on behalf of patients.

2. Programs communicate and cooperate with the criminal justice system in a way that advocates for continuous treatment of incarcerated methadone/LAAM therapy patients as well as those on probation or parole.

XV. Care of Women in Treatment

A. General Principles

1. The policies and procedures of each treatment program reflect the specific needs of female patients.

2. Treatment programs make provisions to provide respectful and safe treatment of women.

3. The use of physical space, including bathrooms, reflects the special needs of female patients.

4. All staff receive intensive training in the specific characteristics and needs of women participating in their particular treatment program.

5. Program policies ensure appropriate clinical flexibility in assigning female patients to counselors who are sensitive to and trained to address their individual needs (e.g., domestic violence, sexual abuse).

6. Program policies and procedures ensure that the option of single sex groups is available to all patients, as needed.

B. Pregnant and Postpartum Patients

Discussion: Pregnant women are still denied methadone/LAAM therapy because program staff are reluctant to initiate medication on an outpatient basis, believing that hospitalization is necessary for induction or withdrawal to ensure that the fetus is not subjected to unnecessary stress. Because it is crucial that these women engage in treatment for their addiction during pregnancy, priority needs to be given to their admission at any point during pregnancy and to providing them with all necessary care, including adequate dosing strategies as well as prenatal and follow-up postpartum services. CSAT also wanted to ensure that pregnant women continue to be excluded from the requirement to demonstrate current physical dependence based on objective signs of opioid withdrawal (see admission criteria).

1. Priority is given to pregnant women who seek treatment; the reasons for denying admission to any pregnant applicant are documented on an intake log.

2. The treatment program ensures that every pregnant patient has the opportunity for prenatal care, provided either onsite or by referral to appropriate health care providers. If referred, the treatment program has agreements in place, including informed consent procedures, that ensure reciprocity in the exchange of pertinent clinical information regarding compliance with the recommended course of medical care.

3. If appropriate prenatal care is not available onsite or by referral, or the pregnant patient cannot afford care or refuses prenatal care services, the treatment program, at a minimum, offers her basic prenatal instruction on maternal, physical, and dietary care as part of the counseling services and documents the provision of these services in the clinical record.

4. If a pregnant patient refuses direct prenatal services or appropriate referral for such care, the treating physician in the methadone/LAAM therapy program may use informed consent procedures to have the patient formally acknowledge in writing that these services were offered but refused.

5. With respect to pharmacotherapy for opioid-addicted pregnant women in methadone/LAAM therapy, the program

a. maintains patients who become pregnant during treatment on the pre-pregnancy dosage, if effective, and applies the same dosing principles as used with any other nonpregnant patient.

b. ensures that the initial methadone dose for a newly admitted pregnant patient and the subsequent induction and maintenance dosing strategy reflect the same effective dosing protocols used for all other patients.

c. monitors the methadone dose carefully, especially during the third trimester when pregnancy-induced changes in the rate at which methadone is metabolized or eliminated from the system may necessitate either an increased or split dose.

d. ensures that if a pregnant patient elects to withdraw from methadone, a physician experienced in addiction medicine supervises the withdrawal process, regular fetal assessments as appropriate for gestational age are part of the withdrawal process, and withdrawal is not initiated before 14 weeks' or after 32 weeks' gestation.

6. The program encourages breast-feeding during methadone/LAAM therapy unless medically contraindicated, e.g., by the presence of HIV or HTLV I and II infection in the mother.

7. The treatment program establishes and implements policies and procedures, including informed consent, to ensure appropriate follow-up and primary care for the new mother and well baby care for the infant.

8. If a pregnant patient is discharged, the program will identify the physician to whom the person served is being discharged. The name, address, and telephone number of the physician should be recorded in the record of the person served.

C. Concurrent Pregnancy and HIV Infection

1. Pregnant women in methadone/LAAM therapy with concomitant HIV infection are subject to the same policies and procedures established for all HIV-infected patients in treatment and receive the same services.

2. Treatment programs offer pregnant patients with AIDS diagnoses the same treatment opportunities and services, directly or by referral, as AIDS-diagnosed patients who are not pregnant.

3. Treatment programs ensure that all pregnant patients with concurrent HIV infection are (1) informed that AZT is currently recommended to reduce perinatal transmission, and (2) provided with appropriate referrals and case management for this treatment.

D. Family Needs

1. The treatment program either offers on-site education and training for all male and female parenting patients, or refers patients to appropriate parenting skills services, and makes appropriate child care services available.

2. Program services include reproductive health education for all patients and appropriate referrals, as needed, for contraceptive services.

XVI. Patients' Rights

A. Principles

1. Patients have the right to treatment that

a. is given with full informed consent;

b. is individualized and participatory;

c. responds adequately to patient needs;

d. promotes dignity and is humane;

e. promotes autonomy and patient responsibility;

f. protects confidentiality;

g. protects and promotes overall health and well-being.

2. Program administration obtains and is responsive to patients' feedback concerning their care.

3. Programs develop and implement policies and procedures to promote and protect patients' rights as well as their health and well-being.

4. Programs must inform patients both verbally and in writing of clinic rules and regulations and patients' rights and responsibilities.

5. Programs establish procedures to cooperate in the medicating of traveling patients.

B. Patients' Rights and Responsibilities

Discussion: Patients undergo sufficient stress during admission that additional opportunities to review their rights and responsibilities are warranted once they are better able to understand them. Patients need this information in multiple formats, appropriate to culture, language, and literacy level. Examples include signs in the waiting room, pamphlets, electronic media (video, tapes), and "talk through" with staff.

At the time of admission, each patient is informed of his or her rights and responsibilities in a language that he or she understands, and receives a written copy of these rights, including the following information.

1. Treatment provided will be fair and impartial regardless of race, sex, age, source of payment, etc., and conveys a sense of dignity and trust between program and patient.

2. Treatment will be provided according to accepted clinical practice.

3. Patients will be fully informed, as evidenced by a patient's written acknowledgment, at the time of admission and during ongoing treatment (once the patient is stabilized), of their rights and responsibilities, and of all the rules and regulations governing patient conduct and responsibilities. Such rights and responsibilities are posted at the treatment site and/or provided to the patient in writing and/or by tape or video or other electronic media as appropriate, and are reviewed with the patient following admission, at the end of the stabilization period, and then if any changes have occurred. Patients who are unable to read have the rules and regulations explained verbally, and such actions documented.

4. Patients will receive adequate and humane services.

5. Patients will receive services within the least restrictive and most accommodating environment possible.

Procedures are in place to ensure the right to a medication schedule (dosing hours/schedule) which is most accommodating and least intrusive and disruptive for **most** patients.

6. Patients will receive an individualized treatment plan, participate in the development of that plan, receive treatment based on the plan, and a periodic, joint staff/patient review of the patient's treatment plan.

7. The program will provide an adequate number of competent, qualified, and experienced professional clinical staff to implement and supervise the treatment plan, consistent with patient needs.

8. Patients will be informed about alternative medications, treatment alternatives, alternative modalities, and scientific advances affecting treatment.

9. Patients will be informed about potential interactions with and adverse reactions to other substances, including those reactions that might result from interactions and adverse reactions to alcohol, other prescribed or over-the-counter pharmacological agents, other medical procedures, and food.

10. Patients will be encouraged and assisted throughout treatment to understand and exercise their rights as a patient, including

    a. reporting, without fear of retribution, any instances of suspected abuse, neglect, or exploitation of patients being served in the program.

    b. a grievance and appeal process, in accordance with State laws and regulations.

    c. input into program policies and services through patient satisfaction surveys.

11. Patients will be informed regarding the financial aspects of treatment, including the consequences of nonpayment of required fees.

12. Patients will be given an assessment, acceptance into the program or, in the case of denial of admission, a full explanation and a referral to another program based upon the results of the initial assessment.

13. Programs have the responsibility to protect other patients, staff and the public from a patient who acts out. However, programs also have a responsibility to determine the cause of that behavior so an appropriate referral to an alternative method of care can be made.

14. **Consumer Bill of Rights and Responsibilities**

The Advisory Commission on Consumer Protection and Quality in the Health Care Industry was appointed by President Clinton on March 26, 1997, to "advise the President on changes occurring in the health care system and recommend measures as may be necessary to promote and assure health care quality and value, and protect consumers and workers in the health care system." As part of its work, the President asked the Commission to draft a "consumer bill of rights." The following rights and responsibilities have been drawn up by the Commission and have been made a part of these guidelines:

a. Information Disclosure

Consumers have the right to receive accurate, easily understood information and some require assistance in making informed health care decisions about their health plans, professionals, and facilities.

b. Choice of Providers and Plans

Consumers have the right to a choice of health care providers that is sufficient to ensure access to appropriate high-quality health care.

c. Access to Emergency Services

Consumers have the right to access emergency health care services when and where the need arises. Health plans should provide payment when a consumer presents to an emergency department with acute symptoms of sufficient severity—including severe pain—such that a "prudent layperson" could reasonably expect the absence of medical attention to result in placing that consumer's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

d. Participation in Treatment Decisions

Consumers have the right and responsibility to fully participate in all decisions related to their health care. Consumers who are unable to fully participate in treatment decisions have the right to be represented by parents, guardians, family members, or other conservators.

e. Respect and Nondiscrimination

Consumers have the right to considerate, respectful care from all members of the health care system at all times and under all circumstances. An environment of mutual respect is essential to maintain a quality health care system.

Consumers must not be discriminated against in the delivery of health care services consistent with the benefits covered in their policy or as required by law based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

Consumers who are eligible for coverage under the terms and conditions of a health plan or program or as required by law must not be discriminated against in marketing and enrollment practices based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

f. Confidentiality of Health Information

Consumers have the right to communicate with health care providers in confidence and to have the confidentiality of their individually identifiable health care information protected. Consumers also have the right to review and copy their own medical records and request amendments to their records.

g. Complaints and Appeals

All consumers have the right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review.

h. Consumer Responsibilities

In a health care system that protects consumers' rights, it is reasonable to expect and encourage consumers to assume reasonable responsibilities. Greater individual involvement by consumers in their care increases the likelihood of achieving the best outcomes and helps support a quality improvement, cost-conscious environment.

C. Privacy

Discussion: Internal controls on privacy are often overlooked in facility design and in staff-to-patient and patient-to-patient communications. Examples include windowed/open work space; cashier in public area; untrained security guards; common medication dispensing areas; and hallway conversations about HIV/AIDS, failed urinalysis, or psychiatric medications.

Patients have a right to privacy, both inside and outside the program setting.

D. Confidentiality

1. Patients have the right to confidentiality in accordance with Federal rules (42 CFR).

2. Patients have the right to be informed of the extent and limits of confidentiality, including the conditions under which information can be released without patient consent, the use of identifying information for purposes of central registry, program evaluation, billing, and statutory requirements for reporting abuse.

E. Informed Consent

1. Patients have the right to give informed consent prior to being involved in research projects, and the right to retain a copy of the informed consent form.

2. Patients have the right to full disclosure of information about treatment and medication, including accommodation for those who do not speak English, or who are otherwise unable to read an informed consent form.

F. Patient Complaints: Preventing, Investigating, and Resolving

Programs develop and display in the patient care area policies and patient grievance procedures that specify minimum elements of due process applicable to the program setting and resources, including the following:

1. The right of patients to express verbally or in writing their dissatisfaction with or complaints about treatment received.

2. The right to initiate grievance procedures.

3. The right to be informed of the grievance procedures in a manner which can be understood, and a right to a copy of the procedures upon request. Such procedures should be clearly articulated, well published, posted in conspicuous places within the program, and easily available to patients. They include program rules, consequences of noncompliance, and procedures for filing a complaint and/or grievance.

4. The right to receive a decision in writing, with the reasoning articulated.

5. The right to appeal the decision to a final, unbiased source.

6. The responsibility of the program to make every attempt, before a patient is discharged, to accommodate the patient's desire to remain in some type of methadone/LAAM therapy at an alternative treatment program.

7. The use of involuntary withdrawal only as a sanction of last resort that is accomplished in the most humane manner consistent with the safety and well-being of staff, other patients, and the program.

8. The patient's methadone dose shall not be changed without the patient's knowledge unless the patient signs a document waiving such consent.

XVII. Record Keeping and Documentation

All records required by the CSAT "Guidelines for the Accreditation of Opioid Treatment Programs" shall be retained for a minimum of 3 years.

A. Patient Records

Patient records are confidential and updated in a timely manner. They contain legible entries, and are organized in a manner that facilitates access to specific elements of the record as well as measurement of individual patient treatment outcomes. Program should have record retention policies and safeguards for the destruction of old containers, labels, printouts, and clinic records. Programs procedures should ensure security of electronic transfers and protection of confidential data stored in the computer.

Individual records maintained for each patient contain the following:

1. Identifying and basic demographic data and results of screening process. In lieu of identification data, each file may bear a unique code or identification reference designation giving ready and sure access to such required identification information. All information should be accessible and understandable to appropriate authorities.
2. Documentation of compliance with the approved central registry system (if applicable), or alternative mechanism to avoid dual registration.

3. The initial assessment report.

4. Narrative bio-psychosocial history prepared within approximately 30 days of the patient's admission or as required by State regulation.

5. Medical reports, including results of physical examination; past and family medical history; review of systems; nursing notes; laboratory reports, including results of regular toxicology screens; and progress notes, including documentation of current dose and other dosage data. Information in the medical record is entered by physicians and other licensed health professionals.

6. Dated case entries of all significant contacts with patients, including a record of each counseling session in chronological order.

7. Dates and results of case conferences for patients.

8. The treatment plan, and any amendments to it; quarterly reviews and updates of the assessment and treatment plan for the first year of continuous treatment; semiannual assessment and treatment plan updates for subsequent years; and, in subsequent years, a semiannual summary by the counselor which includes an evaluation of the existing treatment plan and the patient's response to treatment.

9. Documentation that all services listed in the treatment plan are available and have actually been provided.

10. A written report of the process and factors considered in decisions impacting patient treatment (e.g., "take-home" medication privileges, changes in counseling sessions, changes in frequency of urine tests) or any other significant change in treatment, both positive and negative.

11. A record of correspondence with patient, family members, and other individuals, and a record of each referral for service and its results.

12. Documentation that the patient was provided with a copy of the program's rules and regulations and a statement of patients' rights and responsibilities, and that these items were discussed with her or him.

13. Consent forms, release(s) of information, prescription documentation, travel, employment, and "take-home" documentation, etc.

14. A closing summary, including reasons for discharge and any referral. In the case of death, the cause of death is documented.

B. Records of Storage, Dispensing, and Administering Methadone/LAAM

1. Each program has policies and procedures consistent with DEA statutes and regulations.

2. Each medication order and dosage change is written on an acceptable order sheet signed by the physician.

    a. Each dosage dispensed, prepared, or received is recorded and accounted for by written signed notation in a manner which creates a perpetual and accurate inventory of all methadone in stock at all times.

    b. Every dose is recorded on an administration sheet at the time that the dose is administered or

dispensed and also on the patient's individual medication dose history.

c. The qualified person administering or dispensing signs his or her name or initials at each notation.

d. If initials are used, the full signature of the qualified person administering or dispensing appears at the end of each page of the medication sheet.

e. The substance is totaled in milligrams daily.

3. Programs have a procedure for calibrating medication dispensing instruments consistent with manufacturers' recommendations to ensure accurate patient dosing and substance tracking.

C. Other Records

Discussion: Standard intake forms or identical data elements are used when possible. The objective is to encourage agencies and programs to be efficient and avoid duplication of record keeping while gathering sufficient data for outcome, cross-site, or other evaluations or studies or to support managed care data requirements.

1. Programs maintain individualized personnel files as a record of employment. These files contain employment and credentialing data deemed appropriate by the employer. It is recommended that they contain employment application data and date of employment, updated licensing and credentialing data, detailed job descriptions, performance evaluations, and appropriate intramural and extramural training records.

2. Programs develop and implement procedures to avoid duplication of information gathering without compromising objectives of multiple agencies.

XVIII. Community Relations and Education

Discussion: Before a new program moves in and opens its doors, there is a strong need to educate all entities impacted by the program, including the medical community, neighbors, and those who will be asked to provide support services.

For existing and/or new programs, to help minimize negative impact on the community, promote peaceful coexistence, and plan for change and program growth, programs develop and implement a general set of practices, policies, and procedures that

1. consider community need and impact in siting programs.

2. elicit input from the community on the program's impact in the neighborhood.

3. ensure that the facility's physical appearance is clean and orderly and that the physical setting does not impede pedestrian or traffic flow.

4. identify community leaders for the purpose of fostering good community relations, and establish interpersonal contact, and proactive associations with those identified people. For example:

   a. publicly elected representatives;

   b. local health, substance abuse, social, and/or human service agency directors;

c. business organization leaders;

d. community and health planning agency directors;

e. grassroots community organization leaders;

f. local police and law enforcement officials;

g. religious and spiritual leaders.

5. develop and support a community relations plan specific to the configuration and needs of the program within its community that includes the following steps:

   a. establishing a liaison with community representatives to share information about the program and community and mutual issues;

   b. identifying program personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan;

   c. serving as a community resource on substance abuse and related health and social issues, as well as promoting the benefit of methadone/LAAM therapy in preserving the public health;

   d. soliciting community input about methadone/LAAM therapy and the program's presence in the community;

   e. developing program policies and procedures to effectively address or resolve community problems (including patient loitering and medication diversion), and ensuring that program operations do not adversely affect community life.

6. document community relations efforts and community contacts, evaluate these efforts and contacts over time, and address outstanding problems or deficiencies.

7. devise communication mechanisms so that interested parties and potential patients may obtain general information about the program outside regular operating hours.

8. develop a plan in place for contingencies, emergencies, closure, transportation of staff during poor weather, etc.

XIX. Diversion Control

Each program shall have a diversion control plan that demonstrates accountability and efficient use of personnel and other resources to achieve the highest quality of patient care while reducing possibilities for diversion of controlled substances from legitimate treatment to illicit use. The plan shall include the following:

A. A mechanism for continuous monitoring of clinical and administrative activities, to reduce the risk of medication diversion.

B. A mechanism for problem identification and correction, and for prevention of related diversion problems.

XX. Participation in Opioid (Methadone/LAAM) Therapy Research Activities

Discussion: CSAT emphasized that many treatment programs are not affiliated with academic institutions, are not familiar with the usual requirements of formal research, and may not be comfortable in establishing boundaries for research projects with respect to time constraints or resource limitations. Many programs will need reinforcement or authority to ensure that the characteristics of the program environment and available resources are carefully analyzed and found appropriate before an agreement is reached to conduct any type of formal research or a less formal study.

Since research nearly always interferes to some extent with routine clinical procedures, it is critical that local staff have some authority in determining what comprises the "integrity of the treatment process." Ideally, the program director/manager will explain the proposed research/study to all staff and get their concurrence before deciding if, when, and under what conditions the research can be conducted.

Furthermore, many treatment programs will not be familiar with the usual safeguards and protections afforded to human subjects through the peer-review process and the Institutional Review Board (IRB) review and approval of research grants. Staff at some programs may need training in order to understand Federal human subject protection standards, how to monitor compliance, and who to inform if violations occur. Research participation may need to be terminated prematurely when it becomes harmful or interferes with the integrity of the treatment process.

The Federal human subject protection standards generally assume that (1) all participation in new interventions is voluntary, (2) confidentiality of patient records and research data is assured, (3) written, informed consent is obtained, (4) the risks/benefits of participation are explained to participants, (5) participation does not jeopardize ongoing treatment, and (6) the research does not impose an undue burden on participants. ***(The full Federal human subject protection standards are published in 45 CFR, Part 46.)***

A. Programs are encouraged to participate in research activities as long as they do not compromise the integrity of the treatment process.

B. Research conducted in the treatment program does not compromise the integrity of the treatment process.

C. The director/manager of the treatment program has authority to ensure that the program environment is suitable and receptive to any proposed research or study and that the proposed research is based on sound scientific principles.

D. All research involving human subjects is conducted in accordance with accepted Federal human subject protection standards.

E. Treatment and other services are not jeopardized for any patient who refuses to participate in research activities.

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